AD_____

Grant Number DAMD17-94-J-4449

TITLE: A Randomized Clinical Trial to Evaluate Advance Nursing Care for Women with Newly Diagnosed Breast Cancer

PRINCIPAL INVESTIGATOR: Laurie Ritz, R.N.

CONTRACTING ORGANIZATION: Park Nicollett Medical Foundation
Minneapolis, Minnesota 55416

REPORT DATE: October 1998

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	October 1998	Annual (1 Oct 97 - 30 Sep 98)

4. TITLE AND SUBTITLE
A Randomized Clinical Trial to Evaluate Advance Nursing Care for Women with Newly Diagnosed Breast Cancer

5. FUNDING NUMBERS
DAMD17-94-J-4449

6. AUTHOR(S)
Laurie Ritz, R.N.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Park Nicollett Medical Foundation
Minneapolis, Minnesota 55416

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200*

The purpose of this randomized clinical trial is to evaluate the impact of an advanced practice nurse on the cost of care and quality of life for women newly diagnosed with breast cancer. The control group receives standard medical care while the experimental group receives standard medical care plus advanced practice nursing care. Interventions of the advanced practice nurses (APN) include coordination of care, education, direct care, and support. The two year study has been completed by 135/210 (64%) women. Univariate analyses indicate uncertainty decreased on the Mishel Uncertainty in Illness Scale (MUIS) from baseline significantly more in the intervention group than the control group at 1 month (p=.001), 3 months (p=.026), and 6 months (p=.011) after diagnosis. At 12 months the two groups showed similar decreases in uncertainty (p=.589). The intervention group showed greater reduction of the MUIS sub-scales of complexity, inconsistency, and unpredictability (p=.002, .004, .008 respectively). Changes in mood states and well-being did not differ significantly in the four follow-up periods which have received preliminary analysis. Cost of care data has been collected for 118/210 (56%) participants. After data is collected for the entire sample, analysis of the cost data will begin. Translation of study results into clinical practice is occurring concurrent with interpretation of results. A second study with a modified APN intervention, all analyses, and reporting of all results will be completed 9/30/99 as per statement of work.

14. SUBJECT TERMS	15. NUMBER OF PAGES
Breast Cancer	35
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

FOREWORD

Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the U.S. Army.

__ll__ Where copyrighted material is quoted, permission has been obtained to use such material.

_____ Where material from documents designated for limited distribution is quoted, permission has been obtained to use the material.

_____ Citations of commercial organizations and trade names in this report do not constitute an official Department of Army endorsement or approval of the products or services of these organizations.

_____ In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

__ll__ For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

_____ In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

_____ In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

_____ In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Lawrence J. Ritz — 10/21/98

PI - Signature — Date

TABLE OF CONTENTS

INTRODUCTION

Breast cancer accounts for almost one third of all cancers in women in the United States (US). Greater than 180,000 new cases will be diagnosed and almost 44,000 women will die of breast cancer in 1998.[1] Cost-effective methods to manage care for individuals with breast cancer while continuing to achieve quality outcomes is a major US public health goal. As costs decrease, it is unclear if quality outcomes are being maintained. Factors including access to care, intricacy of the health care system, numerous caregivers, complexities of the diagnostic tests and procedures, technical components of treatment, and multiple personal issues can overwhelm patients and result in compromised quality outcomes.

An Advanced Practice Nurse (APN) could serve as a facilitator to ease the breast cancer patient's way through the health care system by providing quality care in a cost-effective manner. The former Office of Technology Assessment of the US Congress conducted a comprehensive review of 286 studies on the cost and effectiveness of APNs. Their findings from this review indicated that within the APN's area of competence, they communicate better with patients, concentrate more on prevention, and provide more education than physicians. Patients are satisfied with care, access to care is less complicated, and the costs of care are less with the interventions of the APN.[2]

Studies in the US focused on lung cancer patients, low birthweight infants, myocardial infarction patients, cardiovascular surgical patients, HIV-infected individuals, children with chronic diseases, and hospitalized elderly have demonstrated the effectiveness of advanced nursing care with improved outcomes and reduced health care costs, but none have focused on women with breast cancer.[3-11]

A large body of research and literature has focused on dimensions of quality of life (QOL) as outcomes of women with breast cancer. Factors which impact quality of life are physical symptoms including nausea, vomiting, pain, and fatigue, but other variables such as anxiety relating to the diagnosis, anger, hostility, uncertainty, lack of knowledge, change in appearance, and mood alterations also significantly contribute to the distress and compromised QOL of women with breast cancer.[12-19] These variables have led to additional complications in some women such as psychiatric problems, insomnia, suicidal ideations, and alcohol abuse.[20-23] Conflicting reports on the nature and length of adjustment to breast cancer exist with emotional reactions to mastectomy taking two months or less to several years to resolve.[18,24,25] In addition to compromised QOL, physiologic effects of stress inhibit cellular immune responses during the post-operative period.[26] These decreased immune responses related to anxiety may affect survivorship of women diagnosed with breast cancer.

Interventions including education; rehabilitation strategies; coordination of care; home care; counseling; support of health care professionals, family, and friends; spiritual support; and support groups have improved factors which affect QOL of women being

treated for breast cancer.[14,18,21,27-39] An APN could coordinate and provide appropriate interventions for women diagnosed with breast cancer.

Cost-benefit analyses of various treatment approaches have been done to facilitate the decision-making process in cost-effective definitive treatment of women with breast cancer.[40-45] Only one cost-benefit analysis was found in the literature which looked at nurse specialist care of women with breast cancer in England.[45] Psychiatric morbidity of women with breast cancer was substantially reduced by a specialist nurse who counseled women before and after surgery and monitored their progress. The salary of the nurse specialist was offset by savings made by early recognition and treatment of patient complications and decreased loss of employment time by family members of the patient. A similar analysis is required to further study the costs of care of advanced practice nurses with this group of patients in the US health care system and the quality outcomes which are achieved.

The purpose of this study is to evaluate the quality and cost outcomes of the APN with women who are newly diagnosed with breast cancer. Hypotheses which will be tested are:

- Women with newly diagnosed breast cancer who receive continuity of care through advanced nursing care/interventions across the various health care settings will achieve a better quality of life than patients who do not receive advanced nursing care.

- Women with newly diagnosed breast cancer who receive advanced nursing follow-up care/interventions will have a lower cost of care than patients who do not receive advanced nursing care.

METHODS

Setting

The setting for this study is HealthSystem Minnesota, an integrated health care system in a suburban community of Minneapolis, Minnesota. This system is comprised of Methodist Hospital (a 426-bed hospital), Park Nicollet Clinics, Primary Physician Networks, the Foundation, and the Institute for Research and Education. HealthSystem Minnesota employs approximately 6000 people, including more than 450 physicians. It has played a leadership role in cancer care in Minnesota since 1976 when it was first accredited by the American College of Surgeons Commission on Cancer (ACSCC). The Cancer Program is currently designated as a Teaching Hospital Cancer Program by the ACSCC and offers a complete range of diagnostic, treatment, education, research, and support programs.

HealthSystem Minnesota provides care to about 16 percent of Twin Cities residents and serves these residents from more than 31 accessible neighborhood locations. The system does not have a designated payer component but has strong partnerships with several major payers. Approximately 29 percent of its revenue is from government programs including Medicare (25.5%), Medicaid (1.3%), and Minnesota Care (2.3%). The other 71 percent is from purchasers of managed care and traditional fee-for-service plans including Health Partners (32.7%), Blue Cross & Blue Shield (15.8%), Medica (3.2%), Non Contract (8.4%), and other (10.8%).[46] In 1997, in Minnesota, 25.2% of $2.5 billion that Health Maintenance Organizations (HMOs) reportedly paid for health care expenses was paid through capitation arrangements.[47] When comparing premium levels, Minnesota health care is 25-35% lower than national benchmarks.[48]

In addition to this system, Fairview Ridges Hospital (a 150-bed hospital located 25 miles from Methodist Hospital) was added as a site in October 1996. The same HealthSystem Minnesota physicians deliver care at Fairview Ridges for the system's patients in this suburban community and surrounding areas.

Sample

Enrollment to this study is completed. The study sample is female breast cancer patients ≥18 yrs old who were newly diagnosed between February 1995 and May 1997. They were identified through pathology departments of both participating hospitals for potential participation in this randomized clinical trial. Physician referral was requested and eligibility criteria were checked. Participant eligibility required newly diagnosed women to give informed consent, read and write English, and complete questionnaires. Ineligible women had a previous diagnosis of cancer, severe psychiatric illness, or comorbidity limiting functional ability. In addition, enrollment into the study required women to plan their care within the health system and to give their consent within two weeks of diagnosis. Women who participated from the added site of care met the same eligibility criteria as those of the original site. After the eligibility criteria were met and informed consent was obtained, the women were randomly assigned into one of two groups: women in the control group received standard medical care while women in the intervention group received standard medical care plus advanced nursing care.

Intervention

The intervention is advanced nursing care which consists of follow-up care and interventions based on Brooten's work[49] and the standards of advanced practice in oncology nursing.[50] It includes coordination of care, assessment and monitoring of symptoms, direct care, patient and family education, consultation with other health care services, utilization of current research findings, and establishment of standards of practice. Care is individualized to patient and family needs, based on the expressed needs of the individual, the assessment of the APN, and other health care providers'

evaluations. A detailed description of the APN's standard follow-up care for women in this study as previously reported, is in Table 1.

Data Collection

Quality of Life

Quality of life is measured using three questionnaires: the Functional Assessment of Cancer Therapy (FACT-B), Profile of Mood States (POMS), and Mishel Uncertainty in Illness Scale (MUIS). The FACT-B is a 44-item tool measuring self-reported quality of life in individuals with breast cancer. Six sub-scale scores measure physical well-being (0-28), social/family well-being (0-28), relationships with doctors (0-8), emotional well-being (0-20), functional well-being (0-28), and additional concerns (0-36) related to breast cancer. The FACT-B score (0-148) is the sum of the sub-scale scores. Higher FACT-B scores reflect greater well-being.[51]

The Mishel Uncertainty in Illness Scale (MUIS) is a 33-item instrument which measures a person's inability to determine the meaning of illness-related events. Four sub-scales scores (range) measure ambiguity (0-65), complexity (0-35), inconsistency in information provided (0-35), and unpredictability (0-25). The sub-scale scores are added for a total MUIS score (0-160). Higher MUIS scores reflect greater uncertainty.[52]

The Profile of Mood States (POMS) consists of 65 adjectives describing feeling and mood used to identify and assess transient, fluctuating affective states. Six sub-scale scores (range) measure tension-anxiety (0-36), depression-dejection (0-60), anger-hostility (0-48), vigor-activity (0-32), fatigue-inertia (0-28), and confusion-bewilderment (0-28). The vigor-activity sub-scale score is subtracted from the summation of the other five sub-scale scores for a total mood disturbance score (-32-200). Higher POMS scores reflect a greater mood disturbance.[53]

After randomization, the initial set of questionnaires and a pre-stamped return envelope were given to the participants to be returned within one week. Subsequent sets of questionnaires and return envelopes were mailed at intervals of 1, 3, 6, 12, 18, and 24 months after enrollment and were to be returned within one week of receiving them. Women who do not return questionnaires receive reminder letters mailed after two weeks, telephone calls after four weeks, and additional letters and sets of questionnaires as required.

Costs of Care

Costs of care are collected for each study participant for two years after their date of diagnosis. These costs, in the form of charges and reimbursement, come from the two billing systems of HealthSystem Minnesota (hospital and clinic systems) and independent providers who agreed to participate in this study. HealthSystem Minnesota charges are

taken directly from the billing systems. Some independent providers did not agree to provide exact charges for services, so the Current Procedural Terminology (CPT) coding for the service along with the date of service are obtained. From this collected information, charges are assigned using HealthSystem Minnesota Park Nicollet charges.

HealthSystem Minnesota reimbursement for hospital admissions comes directly from the hospital billing system, but reimbursement is calculated for charges from the Park Nicollet clinic billing system and independent providers. The reimbursement is calculated by multiplying clinic and/or independent charges by a collection factor. A collection factor is based on a participant's insurance product and is determined yearly by the net revenue received from the insurance product divided by gross charges assessed to the insurance product.

The costs of care include fees for provider procedure and service, room utilization, radiological procedures, laboratory tests, supplies, medications, and some other professional fees. The professional fees included are fees for a nurse anesthetist, EKG readings performed by a cardiologist, and participating physicians' services. Professional fees not included are non-participating physicians' fees, anesthesiologist fees, and emergency room physician fees.

Upon collecting charges and reimbursement data, this data is categorized into inpatient hospitalizations, outpatient hospital visits, emergency room visits, clinic visits, urgent care visits, and home care visits and referenced to the time frames of 0-6 months, 6-12 months, 12-18 months, and 18-24 months.

Other cost outcomes including the time lost from employment, support services, and telephone call estimates, are obtained from the diaries which patients maintain for the two year period of study.

The APN costs are measured from the APN logs. APNs complete the logs as they provide care for the subjects at hospitalizations, clinic visits, and home visits. APN time is also recorded for telephone calls, administrative work, and travel for home visits. In addition, travel mileage to homes is recorded. The cost of the APN intervention is calculated by using the formula: APN cost ={[salary + fringe] divided by the number of hours worked} divided by 60 min/hour, taking into account rates of pay and percent time worked for each APN. In addition to the cost per minute from visits, telephone, administrative, and travel time for each patient, a travel cost of $. 315 per mile for home care visits will be calculated.

Analysis

Univariate analysis is being performed using the student's t-test for continuous variables and the chi-square test for categorical variables. All tests are two-tailed and are considered statistically significant at $p<0.05$. The quality of life mean FACT-B,

POMS, and MUIS scores are graphed over time for the intervention group and the control group. Potential predictors of quality of life include group assignment (intervention versus control); treatment type; and disease and demographic characteristics. In addition, any characteristics which are distributed unequally in the intervention and control groups at baseline despite randomization, will be examined.

RESULTS

Of the 561 women with newly diagnosed breast cancer who received initial treatment at HealthSystem Minnesota during the study enrollment period, 85 women were not referred by their physicians (15%) and were not approached about the study. After reviewing eligibility criteria of the 476 referred patients, 180 patients were determined to be ineligible. Patients were deemed ineligible for the following reasons: a previous diagnosis of cancer (n=63), planning to go outside of our system for care (n=46), not enrolling in the study within two weeks of knowing about the diagnosis (n=40), having a comorbidity limiting functional ability (n=12), inability to complete questionnaires (n=8), inability to read and write English (n=4), having a severe psychiatric illness (n=4), and/or inability to give informed consent (n=3). Eighty-five (28.7%) of the 296 eligible patients refused participation. The enrolled sample of 211 (71.3%) women met eligibility criteria and agreed to participate. The sample includes 106 patients in the intervention group, and 105 patients in the control group. One patient randomized to the control group was restaged to a non-cancerous condition after enrolling and subsequently withdrew from the study decreasing the control group to 104 patients. The two-year intervention is completed for 67 women who were randomized to the intervention arm of the study and 68 in the control group.

Patient Characteristics

The randomization process produced similar intervention and control groups at baseline. No significant differences were detected between groups in age at diagnosis, race, marital status, or family history of breast cancer (Table 2). Differences in income between women in the control and intervention groups approached statistical significance (p=0.08). Payment sources were categorized based on the primary payer source. Three categories included managed care or HMO, fee-for-service or Non-HMO, and Medicare/Medical Assistance. The two groups did not differ significantly in payer source (Table 2).

Disease status is compared in Table 3. Women in the intervention group had significantly higher Broder's grades (p=0.04) and tended to have a greater extent of disease (p=0.11) than women in the control group.

Chosen treatment options were similar in both the intervention and control group other than the use of hormone therapy (Table 4). More women in the intervention group were treated with hormones than in the control group (p=0.02).

Preliminary Analysis - QOL

Analysis has been initiated on QOL data for all women during the first year of their study participation. This section describes the baseline QOL results followed by the changes in QOL from baseline at 1, 3, 6, and 12 months. Figures 1, 2, and 3 show the mean scores on the MUIS, POMS, and FACT-B respectively, at each time period.

Baseline: Intervention and control groups were similar on QOL measures at baseline. The MUIS and the POMS indicated that at baseline, women in the intervention group had slightly greater uncertainty and mood disturbance than the control group, but neither difference was statistically significant (p=.057 and p =.076, respectively). FACT-B results demonstrated no significant difference in baseline scores between the intervention and control groups (p=.20).

Women with greater extent of disease, based on the SEER staging system [54], had significantly more uncertainty at baseline than those with less disease (p=0.043). Baseline POMS and FACT-B were unaffected by extent of disease. Results of the FACT-B indicated women who decided on a lumpectomy for treatment had significantly greater well-being (higher FACT-B scores) than those who decided on a mastectomy for treatment (p=.028) at baseline. Mood states and uncertainty at baseline were unaffected by surgical treatment choice.

Age, income, family history of breast cancer, tumor size, and presence of positive nodes, had no effect on MUIS, POMS, or FACT-B scores at baseline.

Further analyses will assess in more detail, the factors that predict patients' mood, level of uncertainty, and well-being after being diagnosed with breast cancer.

Changes from Baseline Scores: Analyses of patients' quality of life 1, 3, 6, and 12 months after baseline compared the difference in QOL scores from baseline to each of the follow-up periods. Using difference scores essentially matched patients on baseline scores. The focus of these analyses was the effect of group assignment (intervention and control).

Univariate analyses indicated that uncertainty decreased from baseline significantly more in the intervention group than the control group at 1 month (p=.001), 3 months (p=.026), and 6 months (p=.011). At one month after baseline, the mean MUIS (uncertainty) score decreased for the intervention group but increased for the control group. At 12 months the two groups showed similar decreases in uncertainty from baseline (p=.589). Changes

from baseline in the POMS and FACT-B scales did not differ significantly for intervention and control groups at any of the four follow-up periods analyzed to date.

Multivariate analyses were also conducted on differences from baseline scores, with the variable of most interest being group assignment. There was some appearance of difference between intervention and control groups on income, the use of hormone therapy, extent of disease, and Broder's grade. Because these variables may affect QOL, they along with age, were included as covariates.

When looking at the effect of group assignment, the multivariate analyses indicated significant differences between intervention and control groups with amount of uncertainty decreasing from baseline at 1, 3, and 6 months, even when adjusting for age, hormone therapy, extent of disease, Broder's grade, and income ($p=.001$, .0035, and .0025 respectively). Once again, there were no significant differences between groups on changes from baseline in POMS or FACT-B.

Sub-scale Scores: Each of the three QOL scales included multiple sub-scales. It is possible that intervention and control groups might differ on a particular sub-scale even when the total score on that scale showed no difference. For that reason, t-tests were performed to compare sub-scale scores of intervention and control groups at baseline, and to compare their change from baseline at each follow-up period. Because of the large number of comparisons and concern about experiment-wide error rate, we used $p<.01$ as the critical value for claiming statistical significance on the sub-scale analyses. There were no significant differences between intervention and control groups at baseline on the sub-scales of MUIS, POMS, or FACT-B. Table 5 shows the results of t-tests assessing differences between groups on changes from baseline. By our criterion of $p<.01$, when compared with the control group, the intervention group showed significantly more improvement from baseline in complexity (understanding the system of care), inconsistency (receiving consistent information), and unpredictability (contingency between illness, treatment cues and illness outcome) sub-scales of the MUIS ($p = .002$, .004, .008 respectively). These differences occurred at one month following baseline.

Future analyses of the follow-up data will use repeated measures regression analyses to determine what other factors are important in determining mood, uncertainty and well-being during and after treatment for breast cancer.

Preliminary Analysis - Costs of Care

Cost of care data has been collected for the entire two years on 118/210 current participants. Further collection will involve collecting cost data for the 0-6 month time period on the rest of the participants, followed by the entire time period. After data is collected for the entire sample, preliminary analysis of the cost data will begin.

Rate of Response and Attrition

To date, the response rate for the sets of questionnaires for participants enrolled in the study is 79% (1091/1368). The rate for questionnaire return is closely followed with reminder letters and phone calls to the participants who are not consistently responding.

Questionnaires during their first year of study for all participants have been returned and are tightly clustered around the target time (baseline, 1 month, 3 months, 6 months, and 12 months). Intervention and control groups did not differ significantly in the times at which they returned questionnaires.

Attrition is 12.4% (26/210) which is less than the projected rate (20%). The intervention group has 8 participants lost to attrition with 4 choosing to not complete the study, 3 dying, and 1 moving to an unknown address. The control group has had 18 participants lost to attrition with 17 choosing not to complete the study and 1 dying.

DISCUSSION

Preliminary analyses indicated slightly greater uncertainty and mood disturbance in the baseline measurements of the intervention group than in the control group. Although neither was statistically significant, factors which may be contributing to the difference in the baseline scores will be studied. Factors which have predicted increased psychological vulnerability include younger age at diagnosis, history of high life stress or depression prior to diagnosis, more advanced disease, a family history of breast cancer, and chemotherapy.[22,32] These factors may be contributing to the uncertainty and mood disturbance seen in the baseline intervention group results. To date, age, income, family history of breast cancer, extent of disease, and surgical treatment have been evaluated. Greater extent of disease was significantly related to uncertainty. Other factors did not seem to contribute to the uncertainty or mood disturbance. Women who chose the surgical treatment option of lumpectomy had significantly greater well-being than women who decided on mastectomy at baseline.

The quality of life data for the first year of the APN intervention has identified preliminary answers of the effect of the APN intervention on uncertainty, mood disturbances, and well-being. Uncertainty decreased significantly in the APN group during the first six months after diagnosis. The education and support of patients by the APNs may have reduced uncertainties and fears of these patients. In addition, the nurses frequently advocated for timely reporting of test results and facilitated communication of the results. Their advocacy and facilitation of communication possibly decreased the wait time for results, therefore decreasing uncertainty for women in the intervention group. Phone and/or home care was provided as needed by the APNs to assist women with questions on drain and wound care, exercise, symptom management, and other care concerns. With hospital discharge often occurring within 6-23 hours after surgical

treatment, both women and their physicians felt they did not always hear or remember the discharge instructions regarding their care at home following surgery. The APN education, support, and direct care seemed to alleviate many of these unknowns. The similar decreases in uncertainty shown by intervention and control groups at 12 months may be related to the decreased need for education relating to new information as many of the women were diagnosed with an early stage breast cancer and were not being actively treated 12 months after diagnosis.

Complexity, inconsistency, and unpredictability scores on the MUIS showed significant improvement in the intervention group when compared with the control group from baseline to one month. The APN who provided continuity of care and information across the various settings of care during the first month of treatment may have contributed to women being able to understand and sort through their care, hear consistent information, and better predict the course of treatment.

Changes from the baseline in the POMS and FACT-B scales did not differ significantly between the intervention and control groups in the follow-up periods during the first year. This is an unexpected finding. Uncertainty about illnesses has been found to predict psychological problems[55]. This association is evident in the data from this study as well. At baseline, MUIS is a significant predictor of every sub-scale of POMS and every sub-scale of FACT-B ($p<.01$ for each). One might have expected a significant change in well-being and mood with the significant changes in uncertainty. Lower power due to higher variance in the POMS scale may be contributing to no significant change in our data. Lack of power does not seem to answer our question regarding lack of significant change with the FACT-B. This scale was originally developed with patients with an advanced (Stage III or IV) cancer. Possibly it may not be as sensitive to differences of women with early stage cancer (Stage 0, I or II) which were 58% of the women in the intervention group and 70% of the control group. The clinical value of the interventions seemed apparent as participants frequently verbalized the value of the nurse intervention in their lives and in their sense of well-being. One variable which may contribute to this finding is co-morbidities. Exclusion criteria did not allow participation by women with co-morbidities which limited functional ability and severe psychiatric illness. Co-morbidities which did not exclude study participation were chronic conditions such as diabetes, congestive heart failure, myocardial infarction, back pain, and arthritis. They tend to be associated with adverse effects on many aspects of functioning and well-being and can result in interaction effects.[56,57] They will be further studied to determine their potential association with the results of the APN intervention on mood state and well-being.

Another factor which may be related to the lack of intervention effect on mood and well-being is the effect of the standardized care process for women in both groups as identified in our breast cancer surgery critical path.[58] This predictability in care may improve adjustment to the diagnosis and treatment as was suggested in Christman's study of uncertainty during radiotherapy.[59]

Physician-patient communication and actions are major factors influencing the psychosocial outcomes of women diagnosed with breast cancer.[60] The quality of our health system's patient-physician relationship may be related to the insignificant statistical results of mood states and well-being. Analyses of the actions of a single provider group like the APNs run the risk of ignoring other providers the context and environment in which they practice. The sociocultural, economic, political, and organizational context may affect the outcomes but may be very difficult to sort out these effects from those of the APNs. In addition, even though QOL, psychological status, behavior, knowledge, and utilization are considered to be nurse sensitive patient outcomes, the measures used may not capture these effects.[61,62]

Other potential associations with this finding will need to be further analyzed.

Counseling needs increase with younger age at diagnosis (<55), history of high life stress or depression, more advanced disease, chemotherapy, or history of breast cancer. Other high risk patients who most likely benefit from the intervention include patients with multiple or complex medical diagnoses; no caregiver in the home; a frail or uneducated caregiver; and those who use hospitals or emergency centers for primary health needs.[63] Women with these risk factors in our study sample need to be further studied and potential relationships between women with these risk factors and QOL data analyzed.

Another need is to determine outcomes of a more focused APN intervention during the first six months after diagnosis. This is the purpose of a second study approved and initiated through the support of the DoD as described below.

Study 2

Based on anecdotal information gathered from interventions of the APN with the newly diagnosed breast cancer patients, three time periods have been identified as times of greatest need for focused patient care. These time periods are: (1) when patients are informed of their diagnosis, (2) during the pre-operative and immediate post-operative period, and (3) in conjunction with radiation and chemotherapy treatments. These time periods concur with Holland's crisis points along the illness trajectory.[64] Based on this information, an additional study is being conducted with the original study to operationalize the program of caring for women with newly diagnosed breast cancer utilizing APNs. Three specific objectives of this study are: 1) describe the quality of life experienced by patients with newly diagnosed breast cancer who are included in the APN program of care during the first 6 months following diagnosis, 2) document the amount of time taken by the APN to perform the intervention 3) expand the eligibility criteria from the original study to further generalize the results to other women with breast cancer.

A convenience sample of 50 women newly diagnosed with breast cancer are being recruited to participate during the 6 month period of recruitment.

The APN interventions with the patients are being done in three time periods. In the first time period, the APN meets in consultation with the patient at the time of their diagnosis. The initial contact includes written and verbal information about breast cancer, what to expect in consultation with physicians, decision-making support, answering questions, tour of the clinic setting or hospital as desired, and the use of presence for support. After the initial contact, the APN follows with a telephone call to reinforce the information given and answers questions that the participant may have. The second intervention period begins when definitive surgery is scheduled. The intervention includes an individualized education session which discusses expectations of surgery, side effects such as pain and nausea management, activity and plan of care tailored to individual patient need and to each surgeon's preferences. All patients are entered onto a critical pathway for consistent pre- and post-operative care. Anticipated hospital length of stay is also discussed with the patient. If appropriate, a home care referral is initiated to continue care after surgery. Direct nursing care, coordinated and administered by the APN, is provided to patients including assessment, development of a comprehensive care plan, and application of clinical treatments. Patients are again instructed to call the APN as needed with any questions or concerns. The APN makes a post-operative phone call or home visit to assess the patient's status, reinforce discharge information and provide additional care as needed by the patient. The third intervention period begins prior to initial radiation therapy or adjuvant chemotherapy and continues during active treatment if appropriate. During this period, additional visits or telephone calls are provided as needed by the patients. If the patient does not receive adjuvant treatment, a follow-up phone call is made to identify and assist with other follow-up needs. See Table 6 for further description of the APN intervention in Study 2.

The same quality of life measures are being used in the second study including the MUIS, POMS, and FACT-B. Measurements will be obtained at the initial visit, three months, and six months following enrollment in the study. APN time will be measured as in the original study. A comparison will be made between the amount of time required for the intervention in the initial study to the amount of time in the second study's intervention.

Descriptive statistics will be generated for all variables. To date, 48 of 50 women are enrolled and participating in the second study. Accrual will occur through 11/98 with completion of the intervention by 5/30/99.

Statement of Work Progression

Work is progressing on schedule as per the statement of work. To date 135 of the remaining 210 women have completed study 1. The APN intervention is occurring with each of the women in study 1's intervention group who have not completed the study and women participating in study 2. Both studies will be completed 5/99 (month 56) as will data collection and entry of all participants' responses. Analysis of data will occur 5-9/99 with reporting of results at the completion of analysis (1999, month 60). No problems are anticipated with the completion of this work as per contract.

CONCLUSIONS

This study is progressing according to the statement of work. Preliminary analyses indicate women who have received the APN intervention had a significantly greater improvement in understanding the system of care, received more consistent information and could better predict illness and treatment outcomes ($p = .002, .004, .008$ respectively). Comparisons of mood and well-being between the two groups did not show statistically significant changes even though women in the intervention group frequently verbalized their satisfaction and multiple benefits in receiving APN care. Contributing factors to these results require further study. Costs of care will be analyzed when data collection is completed. A second study with a modified intervention is being conducted at our study site to further support the translation of study results and operationalize the intervention into clinical practice. All results and implications for clinical practice will be reported by 9/30/99.

REFERENCES

1. Landis, S.H.; Murray, T.; Bolden, S; & Wingo, PA. (1998). Cancer statistics, 1998. CA: A Cancer Journal for Clinicians, 48(1), 6-29.

2. Office of Technology Assessment, U.S. Congress. (1986). Nurse Practitioners, Physician Assistants, and Certified Nurse-Midwives: A Policy Analysis. (Health Technology Case Study 37), OTA-HCS-37. Washington, DC: U.S. Government Printing Office.

3. Oleske, DM & Hauck, WW (1988). A population-based evaluation of the impact of interventions for improving care to cancer patients in home settings. Home Health Services Quarterly, 9, 45-61.

4. McCorkle, R; Benoliel, JQ; Donaldson, G; Georgiadou, F; Moinpour, C; & Goodell, B. (1989). A randomized clinical trial of home nursing care of lung cancer patients. Cancer, 64, 1375-1382.

5. Brooten, D; Kumar, S; Brown, LP; Butts, P; Finkler, SA; Bakewell-Sachs, S; Gibbons, A; & Delivoria-Papadopoulos, M. (1986). A randomized clinical trial of early hospital discharge and home follow-up of very low-birth-weight infants. The New England Journal of Medicine, 315, 934-939.

6. Pozen, MW; Stechmiller, JA; Harris, W; Smith, S; Fried, DD; & Voigt, GC. (1977). A nurse rehabilitator's impact on patients with myocardial infarction. Medical Care, 15(10), 830-837.

7. Aiken, LH; Lake, ET; Semann, S; Lehamn, HP; O'Hare, PA; Cole, CS; Dunbar, D; & Frank, I. (1993). Nurse practitioner managed care for persons with HIV infection. Image: Journal of Nursing Scholarship, 25(3), 172-177.

8. Lipman, T. (1986). Length of hospitalization of children with diabetes: Effect of a clinical nurse specialist. The Diabetes Educator, 14, 41-43.

9. Alexander, JA; Younger, RE; Cohen, RM; & Crawford, LV. (1988). Effectiveness of a nurse managed program for children with chronic asthma. Journal of Pediatric Nursing, 3, 312-317.

10. Neidlinger, L; Scroggins, K; & Kennedy, L. (1987). Cost evaluation of discharge planning for hospitalized elderly. Nursing Economics, 5, 225-230.

11. Vaska, P. (1993). The clinical nurse specialist in cardiovascular surgery: a new Twist. AACN, 4(4), 637-644.

12. Ehlke, G. (1988). Symptom distress in breast cancer patients receiving chemotherapy in the outpatient setting. Oncology Nursing Forum, 15(3), 343-346.

13. Coates, A. (1992). Application of quality of life measures in health care delivery. Journal of Palliative Care, 8(3), 18-21.

14. Knobf, MT. (1986). Physical and psychologic distress associated with adjuvant chemotherapy in women with breast cancer. Journal of Clinical Oncology, 4(5), 678-684.

15. Ganz, PA, Schag, CC, Polinsky, ML, Heinric RL, & Flack V. (1987). Rehabilitation needs and breast cancer: The first month after primary therapy. Breast Cancer Research and Treatment, 10, 243-253.

16. Welch-McCaffery. (1985). Cancer, anxiety, and quality of life. Cancer Nursing, 8(3), 151-158.

17. Wyatt G, Kurtz ME, & Liken M. (1993). Breast cancer survivors: an exploration of quality of life issues. Cancer Nursing, 16(6), 440-448.

18. Ferrell BR, Grant MM, Funk BM, Otis-Green SA, & Garcia NJ. (1998). Quality of life in breast cancer survivors: Implications for developing support services. Oncology Nursing Forum, 25(5), 887-895.

19. Gamble, W. (1994, October 20). Overview of the results of the MCCAP (Minnesota Clinical Comparison and Assessment Project) breast cancer study. Tumor Conference.

20. Jamison KR, Wellisch DK, & Pasnau RO. (1978). Psychological aspects of mastectomy. I: The woman's perspective. American Journal of Psychiatry, 135, 432-436.

21. Meyerowitz BE. (1983). Postmastectomy coping strategies and quality of life. Health Psychology, 2, 117-132.

22. Vinokur AD, Threatt BA, Caplan RD, & Zimmerman BL. (1989). Physical and psychosocial functioning and adjustment to breast cancer. Cancer, 63, 394-405.

23. Massie MJ, Spiegel MD, Lederberg MS, & Holland JC (1995). Psychiatric complications in cancer patients. In GP Murphy, W. Lawrence, & RE Lenhard (Eds.), Clinical Oncology (pp 685-698). Atlanta: American Cancer Society.

24. Krouse H & Krouse J. (1989). Cancer as crisis: the critical elements of adjustment. Nursing Research, 31(2), 96-101.

25. Northouse L. (1989). A longitudinal study of the adjustment of patients and husbands to breast cancer. Oncology Nursing Forum, 16(4), 511-516.

26. Anderson BL, Farrar WB, Golden-Kreutz, Kutz LA, MacCallum R, Courtney ME, & Glaser R. (1998). Stress and immune responses after surgical treatment for regional breast cancer. Journal of the National Cancer Institute, 90, 30-36.

27. Barrere CC. (1992). Breast biopsy support program: Collaboration between the oncology clinical nurse specialist and the ambulatory surgery nurse. Oncology Nursing Forum, 19(9), 1375-1379.

28. Feather BL & Wainstock JM. (1989). Perceptions of postmastectomy patients. Part I. Cancer Nursing, 12(5), 293-300.

29. Neuling SJ & Winefield HR. (1988). Social support and recovery after surgery for breast cancer: Frequency and correlates of supportive behaviors by family, friends, and surgeon. Social Science Medicine, 27, 385-392.

30. Young-McCaughan S & Sexton DL. (1991). A retrospective investigation of the relationship between aerobic exercise and quality of life in women with breast cancer. Oncology Nursing Forum, 18(4), 751-757.

31. Weintraub FN & Hagopian GA. (1990). The effect of nursing consultation on anxiety, side effects, and self-care of patients receiving radiation therapy. Oncology Nursing Forum, 17(3), 31-38.

32. Trief, PM & Donohue-Smith, M. (1996). Counseling needs of women with breast cancer: What the women tell us. Journal of Psychosocial Nursing, 34(5), 24-29.

33. Feather BL & Wainstock JM . (1989). Perceptions of post mastectomy patients. Part II. Cancer Nursing, 12(5), 301-309.

34. Derdiarian A. (1987). Informational needs of recently diagnosed cancer patients: A theoretical framework. Part I. Cancer Nursing, 10(2), 107-115.

35. Derdiarian, A. (1987). Informational needs of recently diagnosed cancer patients: Part II. Method and description. Cancer Nursing, 10(3), 156-163.

36. McEvoy MD & McCorkle R. (1990, September 15). Quality of life issues in patients with disseminated breast cancer. Cancer, Supplement 66, 1416-1421.

37. Cooley ME, Muscari Lin, E, & Hunter SW. (1994). The ambulatory oncology nurse's role. Seminars in Oncology Nursing, 10(4), 245-253.

38. Health Care Advisory Board. (1997, March). Women's Health Project #1: Outpatient and 24-hour mastectomy. WHI-006-001.

39. McCorkle R, Jepson C, Maline D, Lusk E, Braitman L, Buhler-Wilerson K, & Daly MM. (1994). The impact of posthospital home care on patients with cancer. Research in Nursing & Health, 17, 243-251.

40. Scanlon EF. (1991). The role of reconstruction in breast cancer. Cancer, 68(5) Suppl 1144-1147.

41. Eddy DM, Hillner BE, Smith TJ, & Desch CE. (1992). High-dose chemotherapy with autologous bone marrow transplantation for metastatic breast cancer. Journal of American Medical Association, 267(15), 2055-2061.

42. Hillner BE & Smith TJ. (1991). Efficacy and cost effectiveness of adjuvant chemotherapy in women with node-negative breast cancer. New England Journal of Medicine, 324(3), 160-168.

43. Tarazi R, Esselstyn CB, Kuivila T, & Hardesty I. (1984). Early hospital discharge following mastectomy. Cleveland Clinic Quarterly, 51(4), 579-584.

44. Goodman AA & Mendez AL. (1993). Definitive surgery for breast cancer performed on an outpatient basis. Archives of Surgery, 128, 1149-1152.

45. Maquire P, Pentol A, Allen D, Tait A, Brooke M, & Sellwood R. (1982). Cost of counseling women who undergo mastectomy. British Medical Journal, 284, 1933-1935.

46. Hoffarth, B. (1998, October). Accounting Services, Health System Minnesota, Minneapolis, Minnesota.

47. Baumgarten A. (1998, June). Minnesota Managed Care Review. Minneapolis, Minnesota.

48. Staff. (1995, June). Are the Twin Cities a stage V marketplace? Integrated Healthcare Report, 1-6.

49. Brooten, D, Brown, LP, Munro BH, York R, Cohen SM, Roncoli, Hollingworth, A.(1988). Early discharge and specialist transitional care. Image: Journal of Nursing Scholarship, 20(2), 64-68.

50. Oncology Nursing Society. (1990). Standards of Advanced Practice in Oncology Nursing, Oncology Nursing Press, Inc.

51. Cella, DF. (1996). F.A.C.T. Manual, Version 3. Chicago, IL: Rush-Presbyterian-St. Luke's Medical Center.

52. Mishel MH & Epstein D. (1990). Uncertainty in Illness Scales Manual, Tucson, AZ: University of Arizona.

53. McNair, DM, Lorr, M, & Droppleman, LF. (1992). Profile of Mood States (POMS) Manual. San Diego, CA: Educational and Industrial Testing Service.

54. Ries, LAG, Kosary, CL, Hankey BF, Miller BA, Harras A, Edwards BK (eds). (1997). SEER Cancer Statistics Review, 1973-1994. Besthesda, MD: National Cancer Institute. HIH Pub. No. 97-27.

55. Mishel MH (1984). Perceived uncertainty and stress in illness. Research in Nursing & Health, 7, 163-171.

56. Stewart AL, Greenfield S, Hays R, Wells, K., Rogers WH, Berry SD, McGlynn, & Ware, JE. (1989). Functional status and well-being of patients with chronic conditions. JAMA, 262(7), 907-913.

57. Strickland, OL. (1997). Challenges in measuring patient outcomes. Nursing Clinics of North America, 32(3), 495-513.

58. Sladek ML, Swenson KK, Ritz, LJ, Schroeder, LM. (Submitted for publication). Development and implementation of a critical pathway incorporating home care nurses for patient undergoing breast cancer surgery in a one-day surer center. Clinical Journal of Oncology Nursing.

59. Christman, NJ. (1990). Uncertainty and adjustment during radiotherapy. Nursing Research, 39(1), 17-20, 47.

60. Schain WS. (1990). Physician-patient communication about breast cancer. Surgical Clinics of North America, 70(4), 917-937.

61. Brooten D & Naylor MD. (1995). Nurses' effect on changing patient outcomes. Image: Journal of Nursing Scholarship, 27(2), 95-99.

62. Carroll TL & Fay VP. (1997). Measuring the impact of advanced practice nursing on achieving cost-quality outcomes: Issues and challenges. Nursing Administration Quarterly, 21(4), 32-40.

63. Day C, McFarlin P, & Friel S. Bridging the gap between hospital and home: Home care and case management. Stanford Nurse, 3-5.

64. Holland J. (1989). Clinical course of cancer. In J. Holland & J. Rowland (Eds.), Handbook of Psychooncology (pp. 75-100). New York: Oxford University Press.

TABLE 1: STANDARD APN FOLLOW-UP CARE

	PHASE I INTRODUCTION		PHASE III FOLLOW-UP IF NO TREATMENT
Frequency	**Pre-surgical meeting @ 0-7 days**	**Frequency**	Radiation, Chemo, Surgery, Plastic Surgery
	Introductory meeting		**Weekly contact for status**
1visit; 1 call	Explanation of BCNC role & availability	weekly	Education, support and assessment
1visit; 1 call	Needs assessment form	x 2-24wks	Pain
1visit; 1 call	Decision making process	x 2-24wks	ROM
1visit; 1 call	Physical assessment form with Hx (PRN)	x 2-12wks	Seroma
hospital visit	Give pt. copy history/current meds	x 2-12wks	Necrosis
hospital visit	Library information given	x 2-26 wks	Oral intake (especially with chemo)
hospital visit		x 2-12wks	Infection
	Follow-up-up plan:	ongoing	Fatigue
	Tentative plan of care:	x 2-26 wks	Prosthesis Information
	Obtain arm measurements bilaterally	x 2-26 wks	Blood counts
daily callx1-2wks	Calendar	x 2-26 wks	**Psychosocial support**
wkly callsx6-8	Accompany to MD visits		Mood
1 visit	Next contact with BCNC (date)	ongoing	Coping
ongoing	Contact during hospitalization	ongoing	Energy level
ongoing	Contact during outpatient visit	ongoing	Referral to Social Services PRN
			Referral to Support Groups in community
1-2 visits	**PHASE II POST OP**	ongoing	**BCNC support during any/all visits**
1-3x/week	**Home visit post-op 24-48 hrs**	ongoing	surgeon, plastics, oncologist, radiation
	Telephone contact during 1st 3-5 days		
	Education	ongoing	**Follow-up visit @ 4-6 weeks (all pts)**
x 1	Signs of infection/inflammation		Physical assessment
daily x 7	Temp		Arm measurements
daily x 7	JP Stripping /Drainage / leakage/	x1-2 visits	Review signs/symptoms of lymphedema
daily x 7	Incisional Pain	PRN	Body image-looked in mirror?
daily x 7	Swelling	x1 or PRN	Prosthesis
daily x 7	Redness	x1 or PRN	Sexuality
daily x 7	Arm ROM/ pain / burning	x1 or PRN	Back to work or normal activity yet?
daily x 7	General well-being	x1 or PRN	Told others?
daily x 7	Mood	1-24 wks	Family
daily x 7	Fatigue	1-4 wks	Friends
daily x 7	Energy level	1-4 wks	Co-workers
daily x 7	Appetite	1-4 wks	Support group?
daily x 7	Comfort/pain control/ constipation	1-24 wks	**Follow-up with oncologist**
weekly	Coping with life and home	ongoing	Support
weekly	Spouse/significant other	ongoing	Treatment discussion
weekly	Family issues	ongoing	Options
weekly	Children	ongoing	Reinforce education
weekly	Child care	ongoing	Wigs
weekly	Job/career	2-24wks	Cosmetics/hair care
weekly	Housework	ongoing	Fatigue management
X1	**Have they met with reach to recovery**	ongoing	Hot flashes and management
weekly	Exercise/ review with pt /	ongoing	**Follow-up with Plastic Surgeon**
x2	Prosthesis	ongoing	Monitor for necrosis
	Follow-up surgeon visit date?	ongoing	Monitor for infection
5 visits/ ongoing	**Medical plan of care:**	ongoing	Assess for normal ADL's
	RT	ongoing	Pain control with saline expansion
	Chemo	ongoing	Plan for secondary surgery PRN
	Additional Surgery		
	Next FU visit scheduled?		

TABLE 1 CONTINUED: STANDARD APN FOLLOW-UP CARE

PHASE III TREATMENT MANAGEMENT		PHASE IV FOLLOW-UP CARE
Frequency		**Frequency**
monthly FU	**Tamoxifen**	Telephone contact every other wk x 4
0-2 yrs	Side effects: Hot flashes, weight,	(every week x 4 if no treatment; then qow
	mood swings, endometrial ca risk	ongoing Monthly FU phone calls or visits for all pts
	GYN evaluation if spotting	ongoing Lymphedema FU every 3 mos x 4; then q 6
daily x1-3	**Chemo: Call day 1,2,3**	ongoing BSE instruction with return demo PRN
weekly 0-32	Assess nausea, fatigue, diet, activity,	give shower cards, stickers
& monthly	diarrhea, constipation, mouth sores	ongoing Mammogram scheduled annually
	Blood counts	ongoing Stress importance of BSE and FU care
	Educate regarding plan & ttment delays	monthly **ISSUES: support, assess and educate**
FU weekly	**Radiation Therapy:**	ongoing Diet
0-10 weeks	Assess skin reaction, fatigue,	ongoing Exercise
	blood counts	ongoing Weight
0-10 weeks	Educate regarding ttment plan and FU	ongoing Hot flashes
		ongoing Sexuality
monthly	**Educational reinforcement**	ongoing Pregnancy
ongoing	**Frequency of healthcare visits:**	ongoing Work Issues
ongoing	Strategy for coping	ongoing Menopause
ongoing	Activity adjustment	ongoing Insurance coverage
ongoing	Fatigue management	ongoing Medication cost
		ongoing Venous access device management
monthly	**Activity of daily life**	ongoing Late treatment effects
ongoing	Ability to perform ADL's	monthly **Health Promotion**
ongoing	Appearance	ongoing Quit smoking
ongoing	Fatigue	ongoing Diabetic control
ongoing	Energy level	ongoing Assess hypertension
ongoing	Change from precancer level of activity	ongoing Dietary modifications
ongoing	Diet adjustment	ongoing Stress reduction
ongoing	Oral rinse and mouth care	monthly **Complementary therapies**
ongoing	Fluid intake	ongoing Stress management
ongoing	Monitor output	ongoing Imagery
ongoing	Taste changes	ongoing Positive thinking
ongoing	Weight gain/loss	ongoing Support groups
ongoing	Social adjustment	monthly **Recovery**
ongoing	Sick leave availability	ongoing Taking control/proactive
ongoing	Child care issues	ongoing Fear of recurrence
ongoing	Transportation to treatment	ongoing Coping
ongoing	Cooking	ongoing Spirituality
ongoing	Cleaning	ongoing Hope
ongoing	Laundry	monthly **Psychosocial assessment:**
ongoing	Shopping	ongoing Kids
ongoing	other	ongoing Sex
monthly	**Physical side effects**	ongoing Work
ongoing	Skin care:	ongoing Home
ongoing	Rashes	ongoing Reconstruction
ongoing	Incision	ongoing Future plans
ongoing	Dryness	ongoing Social Services referral PRN
ongoing	Neuropathy	
ongoing	Status of surgical site	

TABLE 2. PATIENT CHARACTERISTICS

VARIABLE	INTERVENTION GROUP n=106	CONTROL GROUP n=104	P VALUE
Mean age at diagnosis (yr)	55.7	55.3	0.79
Mean years of education	14.1 (n=103)	14.3 (n=91)	0.61
Mean tumor size (cm)	2.0	2.1	0.57
	n (%)	**n (%)**	
Age (yr)			0.97
<40	9 (8.5)	11 (10.6)	
40-49	24 (22.6)	25 (24.0)	
50-59	34 (32.1)	31 (29.8)	
60-69	25 (23.6)	22 (21.2)	
70-79	13 (12.3)	13 (12.5)	
>79	1 (0.9)	2 (1.9)	
Race			0.90
White	103 (97.2)	101 (97.0)	
Asian	2 (1.9)	1 (1.0)	
African American	1 (0.9)	1 (1.0)	
American Indian	0 (0.0)	1 (1.0)	
Marital Status			0.76
Single, never married	11 (10.4)	15 (14.4)	
Married	74 (69.8)	70 (67.3)	
Divorced	8 (7.5)	9 (8.7)	
Widowed	13 (12.3)	10 (9.6)	
Family history of breast cancer			0.34
Yes	46 (43.4)	52 (50.0)	
No	60 (56.6)	52 (50.0)	
Income			0.08
Below $31,000	24 (22.6)	26 (25.0)	
$31,000-50,999	22 (20.8)	22 (21.2)	
$51,000-70,999	21 (19.8)	7 (6.7)	
$71,000-90,999	11 (10.4)	17 (16.3)	
$91,000 or more	18 (17.0)	14 (13.5)	
Not provided	10 (9.4)	18 (17.3)	
Insurance			0.70
HMO	60 (56.6)	53 (51.0)	
Non-HMO	22 (20.8)	26 (25.0)	
Medicare/Medical Assistance	24 (22.6)	25 (24.0)	

TABLE 3. DISEASE STATUS

VARIABLE	INTERVENTION GROUP n=106	CONTROL GROUP n=104	P VALUE
Extent of disease (SEER Stage)			0.11
In situ	12 (11.3)	8 (7.7)	
Localized	49 (46.2)	65 (62.5)	
Regional	43 (40.6)	29 (27.9)	
Distant	2 (1.9)	2 (1.9)	
Histology			0.37
Non-invasive	12 (11.3)	8 (7.7)	
Invasive	94 (88.7)	96 (92.3)	
Broder's Grade			0.04
Grade 1, well differentiated	15 (14.2)	16 (15.4)	
Grade 2, moderately diff.	55 (51.9)	41 (39.4)	
Grade 3, poorly differentiated	29 (27.4)	45 (43.3)	
Grade 4, undifferentiated	7 (6.6)	2 (1.9)	
Tumor Size			0.43
< 2 cm	62 (58.5)	54 (51.9)	
2 - 5 cm	38 (35.8)	46 (44.2)	
>5 cm	6 (5.7)	4 (3.9)	
No. of positive nodes			0.49
None	56 (52.8)	65 (62.5)	
1-3	26 (24.5)	19 (18.3)	
4-9	9 (8.5)	6 (5.8)	
>9	6 (5.7)	5 (4.8)	
Not assessed	9 (8.5)	9 (8.6)	

TABLE 4. TREATMENT OPTIONS

VARIABLE	INTERVENTION GROUP n=106	CONTROL GROUP n=104	P VALUE
Definitive Surgical Treatment			0.34
Mastectomy	49 (46.2)	55 (52.9)	
Lumpectomy	57 (53.8)	49 (47.1)	
Radiation Therapy			0.22
Yes	68 (64.2)	58 (55.8)	
No	38 (35.8)	46 (44.2)	
Chemotherapy			0.41
Yes	46 (43.4)	51 (49.0)	
No	60 (56.6)	53 (51.0)	
Reconstruction			0.21
Yes	18 (17.0)	25 (24.0)	
No	88 (83.0)	79 (76.0)	
Hormone Therapy			0.02
Yes	62 (58.5)	44 (42.3)	
No	44 (41.5)	60 (57.7)	

TABLE 5: RESULTS OF T-TESTS ASSESSING DIFFERENCES BETWEEN INTERVENTION AND CONTROL GROUPS IN CHANGE FROM BASELINE ON QOL SUBSCALES

	1 month	3 months	6 months	12 months
MUIS:				
Ambiguity	t=1.88, p=.061	t=1.30, p=.195	t=-1.54, p=.125	t=-0.04, p=.969
Complexity	t=3.21, p=.002	t=2.39, p=.018	t=2.04, p=.043	t=1.06, p=.290
Inconsistency	t=2.95, p=.004	t=2.03, p=.044	t=1.60, p=.112	t=-0.22, p=.829
Unpredictability	t=2.70, p=.008	t=1.60, p=.113	t=2.57, p=.011	t=1.25, p=.211
POMS:				
Tension-anxiety	t=0.97, p=.332	t=1.79, p=.075	t=1.14, p=.256	t=0.78, p=.437
Depression-dejection	t=1.98, p=.050	t=1.53, p=.127	t=0.97, p=.332	t=0.25, p=.806
Anger-hostility	t=0.97, p=.333	t=1.64, p=.102	t=1.64, p=.103	t=0.77, p=.444
Vigor-activity	t=-0.11, p=.911	t=0.52, p=.605	t=-0.13, p=.897	t=-0.07, p=.943
Fatigue-inertia	t=0.46, p=.644	t=-0.13, p=.895	t=-0.27, p=.790	t=0.17, p=.864
Confusion-bewilderment	t=1.09, p=.275	t=0.94, p=.347	t=1.09, p=.278	t=0.26, p=.798
FACT-B:				
Physical well-being	t=-0.90, p=.368	t=-0.01, p=.992	t=-0.87, p=.385	t=1.22, p=.224
Social/family well-being	t=-1.17, p=.244	t=-1.04, p=.298	t=-0.62, p=.537	t=1.22, p=.223
Relationship with doctors	t=0.91, p=.365	t=-0.67, p=.506	t=0.43, p=.666	t=0.56, p=.575
Emotional well-being	t=-1.19, p=.237	t=-0.46, p=.649	t=0.03, p=.978	t=1.36, p=.176
Functional well-being	t=-0.92, p=.357	t=-0.21, p=.833	t=-0.64, p=.522	t=0.94, p=.350
Additional concerns	t=-0.53 p=.600	t=0.20, p=.845	t=-0.13, p=.897	t=0.56, p=.574

Note: Differences that were significant at the $p<.01$ level are underlined. The significant differences were in the predicted direction: Intervention group showed more improvement from baseline than Control group.

TABLE 6: APN BREAST CANCER CARE - STUDY 2

All phases are general to patients who are diagnosed with stage O-IV breast cancer. These phases may coincide with each other and may not occur in the order given.

Frequency	
	Phase I Introduction (following initial diagnosis)
Day 1	Breast Cancer Information packet *
Day 1	Explanation of BCNC role & availability *
Day 1	Needs assessment of patient/family (emotional support, finances, work issues, etc.)
Day 1	Psychosocial support (availability of support groups, etc.)
Day 1	Provide access to resources/information
Day 1	Support in decision making process
Day 1	Provide a medical history record *
Day 1	General education on breast cancer, diagnostic tools & its treatment
Day 1	Initiate teaching record *
	Phase II Prior to Surgery
prn	Psychosocial support
prn	Support in decision making process
prn	Accompany to MD visits, prn (presence for support)
prn	Coordinate scheduling of MD visits
x1	Preoperative education *see Care Guide for Breast Cancer Surgery
	Care of incisions & drains (use breast model with Jackson-Pratt)
	Pain management
	Post-op activity
	Anticipation of arm exercises
	Recovery
	Education on breast cancer
	Care Package *
	Lymphedema
	Potential postoperative complications
x1	Initiate Critical Pathway *
x1 & prn	Initiate Reach to Recovery referral; Cansurmount, prn
x1 & prn	Assessment of home environment & transportation; referral prn
	Phase III Postoperative Period (0-2 weeks)
Day 1 +	Hospital visit or phone call for assessment
	Signs of infection/inflammation
	Ability to manage drains/incisions
	Pain management
	Nausea management
	Arm ROM
	General well-being (coping, activity, diet)
	Surgical/reconstructive sites
prn	Home visit, prn
prn	Reinforce education
prn	Psychosocial support, e.g., anxiety with pending path report
x1 & prn	Assessment of needs (work issues, housework, child care, caregiver, etc.)
prn	Collaborate with health care providers

TABLE 6 CONTINUED: APN BREAST CANCER CARE- STUDY 2

Frequency	
	Phase III (continued): Postoperative Period (0-2 weeks)
prn	Advocate for patient
prn	Reach to Recovery follow-through (e.g., need for prosthesis)
prn	Coordinate follow-up MD appointments (Oncology/Radiation Therapy)
x1 & prn	Education on pathology report
	Phase IIIB
	If additional surgery is required, repeat Phases II & III
	Phase IV Post-op (2+ weeks)
x1	Attend oncology visit, prn
x1 & prn	Collaborate with oncology regarding patient's health status
x1 & prn	Education, support, & assessment
	Pain
	ROM
	Seroma development
	Necrosis
	Diet
	Infection/cellulitis
	Fatigue
	Prosthesis information
	Reinforce lymphedema prevention/management
	Diagnostic tests
	Body image
	Short- & long-term implications of surgery
	Pain control with saline implants
	Potential for additional reconstructive surgery
prn	Referrals prn (Social Services, support groups)
	Phase V Systemic Treatment (may include neoadjuvant therapy)
x1	Education on systemic treatment options & mechanism of action
	Provide written information
prn	Assist/support in decision making regarding adjuvant therapy
	Provide information on availability of clinical trials
x1 & prn	Education on management of side effects
	Fatigue
	Alopecia/skin/nail care
	Blood count changes
	GI alterations
	Stomatitis
	Nutritional needs
	Neuropathy/myalgias
	Body image, sexuality, reproduction, & menopausal symptoms
prn	Education on venous access devices

TABLE 6 CONTINUED: APN BREAST CANCER CARE- STUDY 2

Frequency	
	Phase V (continued): Systemic Treatment (may include neoadjuvant therapy)
x1 & prn	Psychosocial needs (insurance/medication issues, coping, etc.)
x1 & prn	Education on long-term side effects (secondary cancers, reproduction, etc.)
x1 & prn	Resuming activities during chemotherapy treatments
x1 & prn	Role of caregiver (e.g., drive to first chemotherapy treatment, role changes, etc.)
prn	Referrals prn (Complementary Medicine, Look Good Feel Better, etc.)
	Chemotherapy (accompany to first chemotherapy treatment)
day 1 & with each cycle	Phone call/hospital visit for assessment/management of complications
prn	Educate regarding treatment plan & treatment delays
x1	Offer log of blood counts
prn	Referrals, prn (physician, complementary medicine, psychosocial support)
every 3 wks. X 4-8 times	Accompany to subsequent oncology visits during chemotherapy, prn
every 3 wks. X 4-8 times	Follow labs and phone call to reinforce education, prn
	Hormonal therapy
week 1 x1	Phone call 1 week following initiation for assessment/management of complications
	Phase VI Radiation Therapy
x1 & prn	Accompany to initial consult & prn
x1	Education on mechanism of action
x1	Education on short & long-term implications
week 1 & prn	Assessment/management of complications
up to 8 weeks	Skin
	Fatigue
	Blood counts
	Phase VII Advanced Disease
prn	Educate on available treatment options
prn	Assist & support decision making process
x1 & prn	Psychosocial support
x1 & prn	Assessment of needs & referrals (home care, hospice, finances, etc.)
x1 & prn	Pain/symptom management
prn	Initiate, coordinate, or attend family conferences
prn	Advocate for patient wishes/advanced directive
prn	Preparation for end of life (e.g. funeral arrangements, mental preparation, etc.)
prn	Assist staff to promote comfort
prn	Assess & obtain medical supplies/equipment
	Phase VIII Ongoing Issues
x1	Educate on follow-up visits/exams
prn with follow-up calls	Health Promotion
	Smoking cessation
	Exercise
	Diet
	Mammography/CBE/BSE

TABLE 6 CONTINUED: APN BREAST CANCER CARE- STUDY 2

Frequency	Phase VIII (continued): Ongoing Issues
prn with follow-up calls	GYN exams
x1 & prn	Survivorship
	Work issues/Insurance issues
	Stress management
	Diabetes management
	Hope
	Spirituality
	Normalcy
	Proactive with breast causes
	Fear of recurrence

FIGURE 1: Mean MUIS scores with 95% confidence limits for intervention and control groups at baseline and at 1, 3, 6, and 12 months following baseline. Higher scores indicate greater uncertainty.

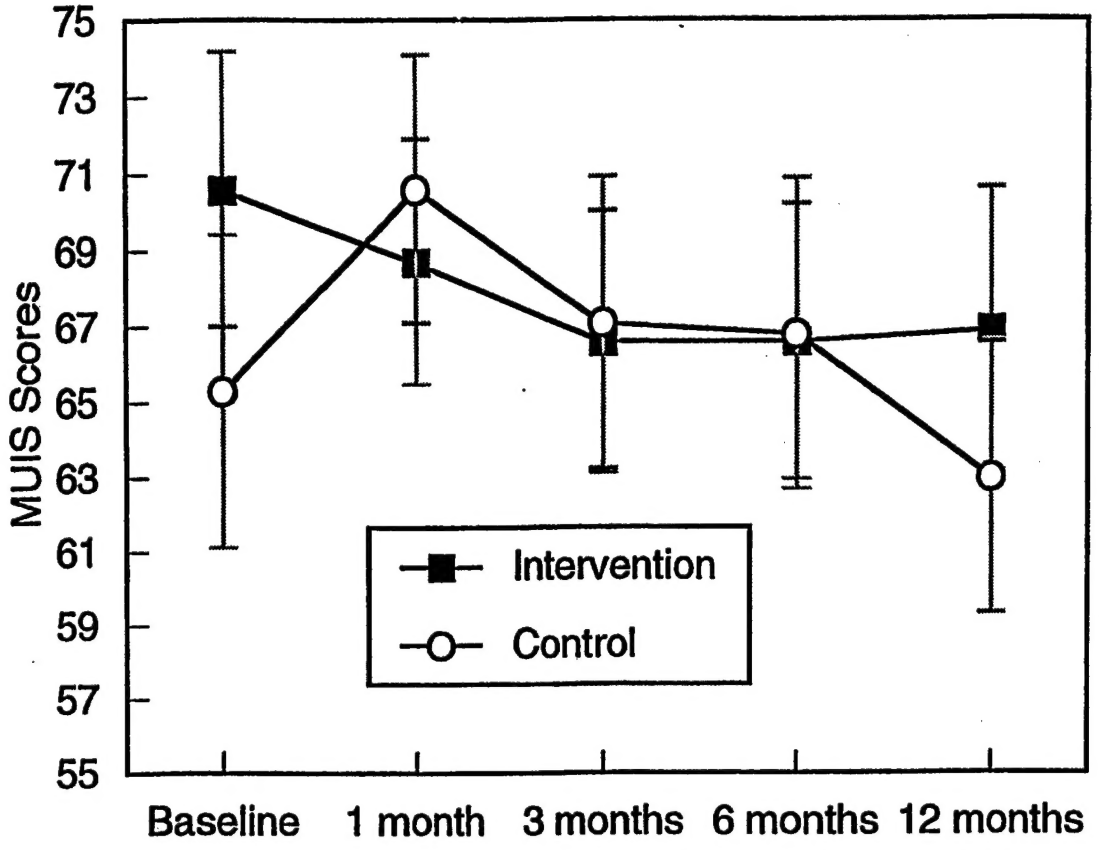

FIGURE 2: Mean POMS scores with 95% confidence limits for intervention and control groups at baseline and at 1, 3, 6, and 12 months following baseline. Higher scores indicate greater mood disturbance.

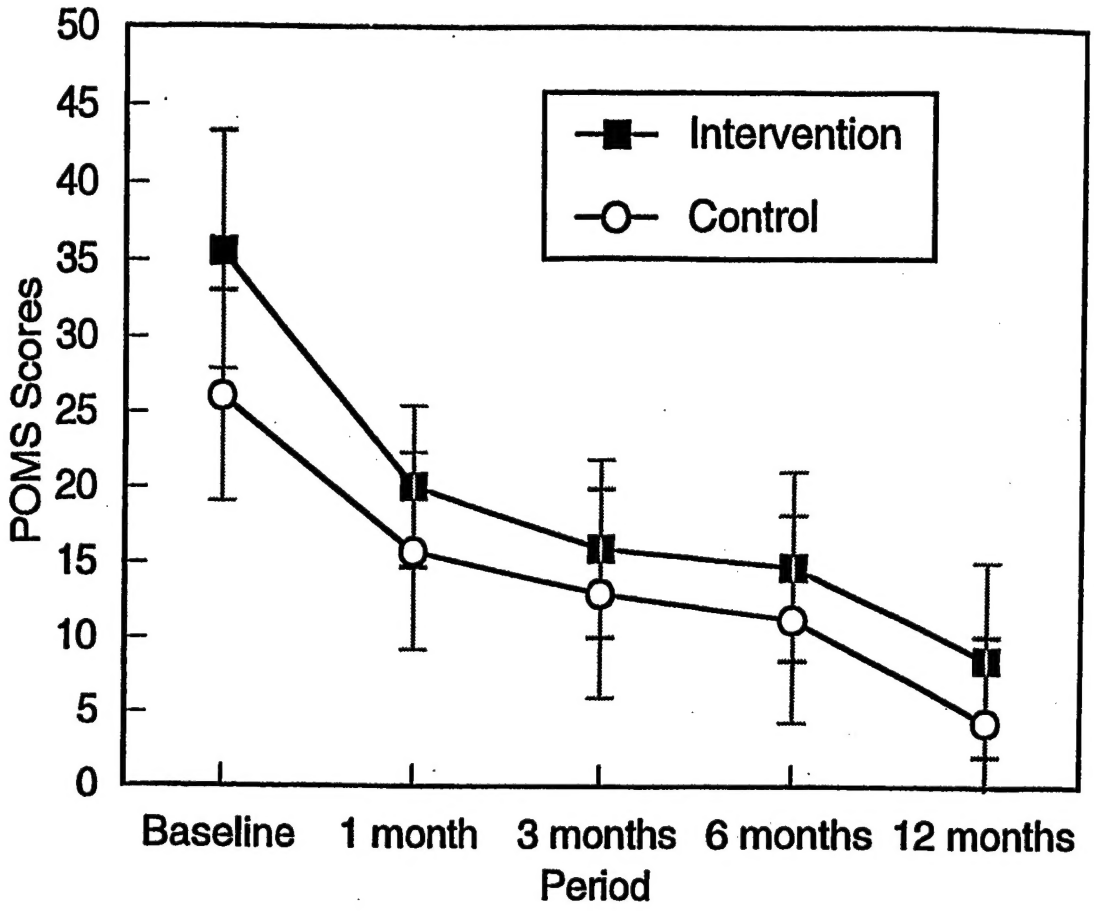

FIGURE 3: Mean FACT-B scores with 95% confidence limits for intervention and control groups at baseline and at 1, 3, 6, and 12 months following baseline. Higher scores indicate greater well-being.